Proposed Modifications to the July 13, 2000 Federal Register Notice

[Federal Register: July 13, 2000 (Volume 65, Number 135)] [Proposed Rules]
[Page 43259-43261]
Page 43259]]

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
7 CFR Part 205
[TM-**00**-04] RIN 0581-AA40

Submission of Petitions for Evaluation of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling
AGENCY: Agricultural Marketing Service, USDA.
ACTION: Notice of Guidelines and Call for National List Petitions.

SUMMARY: The Organic Foods Production Act of 1990, as amended, (Act) requires the Secretary of Agriculture (Secretary) to establish a National List of Allowed and Prohibited Substances (National List) which identifies the synthetic substances that may be used, and the nonsynthetic substances that cannot be used, in organic production and handling operations. The Act authorizes the National Organic Standards Board (NOSB) to develop and forward to the Secretary a recommended Proposed National List, and subsequent proposed amendments to it. The Act provides that persons may petition the NOSB to evaluate a substance for inclusion on or removal from the National List. This notice explains who can submit a petition, for what substances a petition can be submitted, and the information that should be included in a submitted petition. All submitted petitions will be evaluated by the Department of Agriculture's (USDA) National Organic Program (NOP) for completeness. If there is incomplete information, petitioners will be given a reasonable opportunity to provide the missing information. Petitioners should realize that providing incomplete information may increase the evaluation time or result in no substance evaluation. This notice also provides the name and address of the person to whom a petition should be submitted.

ADDRESSES: Petitions should be submitted in duplicate to: National Organic Standards Board, c/oArthur Neal, Agricultural Marketing Specialist, USDA/AMS/TM/NOP, Room 4008-So., Ag Stop 0268, 1400 Independence Avenue, S.W., Washington, D.C. 20250–0200. Phone: 202/720-3252. Fax: 202/205-7808. e-mail: nlpetition@usda.gov. Petitioners are encouraged to submit the required information through one system of submission (mail, fax or e-mail).

FOR FURTHER INFORMATION CONTACT: Richard Mathews, Associate Deputy Administrator, National Organic Program, USDA/AMS/TM/NOP, Room 4008-So., Ag Stop 0268, 1400 Independence Avenue, S.W., Washington, D.C. 20250–0200. Phone: 202/720-3252. Fax: 202/205–7808. e-mail: Richard.Mathews@usda.gov.
SUPPLEMENTARY INFORMATION: To help readers better understand the petition process, we have provided answers to some frequently asked questions about the National List and the petition process.

What Is the Purpose of This Notice?

The NOSB submitted a Proposed National List to the Secretary that was subsequently published on March 13, 2000, as part of the NOP proposed rule, 65 FR 13512-13658, (2000). The Proposed National List was modified based on public comment and finalized in the Final Rule , 65 FR 80548-80864 (2000). A proposed rule was published July 13, 2000, 65 FR 43259-43261, that gave notice of guidelines and called for petitions to amend the National List. This notice amends that initial proposed rule [Final rule??] Substances that are petitioned and under evaluation by the NOSB will be announced on the NOP website: www.ams.usda.gov/nop. Interested individuals or groups can provide information or commentary to the NOSB or NOP for any substance being evaluated by the NOSB.

How Are National List Decisions Made?

The NOSB reviews information from various sources in evaluating substances for inclusion on or removal from the National List. Sources include Technical Advisory Panels (TAP), the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and the testimony of the public. TAP reviews assist the NOSB in evaluating substances being considered for addition to or removal from the National List. The NOP, on behalf of the NOSB, establishes contracts to conduct the TAP with qualified individuals or organizations who have specialized knowledge of the petitioned substances. These reviewers have expertise in such fields as organic production and handling, veterinary medicine, chemistry, or food handling and preparation. All contractors, whether an individual or an organization, must meet USDA contract requirements including the prevention of conflict of interest. The NOP on behalf of the NOSB may contract with any individual or organization having the necessary technical expertise to conduct TAP reviews for NOSB substance evaluations. TAP reports and the NOSB recommendations for each substance are submitted to the Secretary. The Secretary evaluates the recommendations and other documentation regarding each substance for inclusion on or removal from the National List. The Act requires that the initial Proposed National List and subsequent proposed amendments to it be published in the Federal Register for public comment.

How Long Can a Substance Appear on the National List and Will the List Change?

The Act (7 U.S.C. 6517(e)) requires that substances appearing on the National List be reviewed by the NOSB and the Secretary at least once every 5 years following implementation of the NOP. Once a substance evaluation is completed and a recommendation is forwarded to the Secretary, the NOSB will not reevaluate its decision within the 5 year period unless substantive new information becomes available.

What Criteria Does the NOSB Use to Evaluate Petitioned Substances?

The Act (7 U.S.C. 6517 and 6518(m)) requires that the NOSB consider the following criteria for each substance evaluated:

6517(c)(1) (A) …the use of such substance

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

B) the substance

(i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock paraciticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers;

(ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern; or

(iii) is used in handling and is non-synthetic but is not organically produced;

6518(m)(1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems; (2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment; (3) The probability of environmental contamination during manufacture, use, misuse or disposal of such substance; (4) The effect of the substance on human health; (5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the substance's physiological effects on soil organisms (including the salt index and solubility of the soil), crops and livestock; (6) The alternatives to using the substance in terms of practices or other materials; and, (7) It's compatibility with a system of sustainable agriculture.

How Does the NOSB Evaluate Substances Such as Processing Aids or Adjuvants?

In addition to the criteria cited in the Act, criteria for substances used in food processing and handling are included in the regulation at 205.600(b).

(1) The substance cannot be produced from a natural source and there are no organic substitutes;
(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;
(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;
(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
(6) The substance is essential for the handling of organically produced agricultural products.

(c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

When Can the NOSB be Petitioned?

The NOSB can be petitioned at any time for substances not previously evaluated by the NOSB. For substances receiving a prior recommendation by the NOSB restricting or prohibiting its use, a petition may be **filed** only when significant new information may alter the established NOSB recommendation. However, the NOSB and the NOP expects that amending the National List will be a continuous process. For instance, the National List may need to be amended to accommodate development of new substances or technologies in organic production or handling

of foods. Recommendations to amend the National List result from the review and deliberation of the TAP reports and other information by the NOSB Committees (Crop, Livestock, Processing or Materials). These committees forward their recommendations to the entire NOSB which considers, then accepts, modifies or rejects these recommendations during scheduled public meetings or conferences conducted periodically, as needed.

Who Can Submit a Petition?

Any person may submit a petition. Each substance to be evaluated must be submitted in a separate petition.

To Whom Should a Petition be Submitted?

Petitions should be submitted in duplicate to: National Organic Standards Board, c/o Arthur Neal, Agricultural Marketing Specialist, USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268, P.O. Box 96456, Washington, D.C. 20090-6456. Phone: 202/720-3252. Fax: 202/205-7808. e-mail: nlpetition@usda.gov.

What Are the Substances for Which a Petition May be Submitted?

Only single substances or ingredients (generic substances, not brand name products) may be petitioned for evaluation. Formulated products cannot appear on the National List. Substances that appear on USDA's current Proposed National List, 65 Fed. Reg.13626-13628 (2000), should not be petitioned for inclusion on the National List.

What Information Has to be Included in the Petition?

A petition seeking evaluation of a substance must indicate within which of the following categories the substance is being petitioned for inclusion on or removal from the National List:

(1) Synthetic substance's allowed for use in organic crop production;
(2) Nonsynthetic substances prohibited for use in organic crop production;
(3) Synthetic substances allowed for use in organic livestock production;
(4) Nonsynthetic substances prohibited for use in organic livestock production; and
(5) Nonagricultural (nonorganic) substances allowed in or on processed products labeled as ``organic" or ``made with organic (specified ingredients).”
(6) Nonorganically produced agricultural products allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients).”
(7) A person may also submit a petition to add, remove, or change an annotation to a substance currently on the National List.

The petition must also include, as applicable, the following information:

1. The substance`s common name.
2. The petitioner’s`s name, address and telephone number.
3. . The intended or current use of the substance, according to categories in OFPA 6517(c)(1)(B) or NOP 205.601- 205.606, as applicable. Include an explanation of how it is utilized in an organic system.
4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance`s mode of action must be described.
5. . The source of the substance and a detailed description of all manufacturing or processing procedures from the basic component(s) to the final product. Petitioners

with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.

6. A summary of any available previous reviews by International, State or private certification programs or other organizations of the petitioned substance.
7. Information regarding regulatory status under applicable EPA, FDA, and State statutes and regulations, including registration numbers.
8. The Chemical Abstract Service (CAS) number, International Numbering System for food additive (INS number), or other product numbers of the substance and labels of products that contains the petitioned substance. Labels for multiple manufacturers should be submitted if available.
9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use and the impacts of all substances used during manufacture of the substance; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.
[suggest possibly rework #9, #10, #11 to specifically address all OFPA and rule criteria]
10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.
11. . Research information about the substance that includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.
12. A ``Petition Justification Statement'' which provides justification for one of the following actions requested in the petition:

When petitioning for the inclusion of a synthetic substance on the National List, the petition should state why the synthetic substance is necessary for the production or handling of an organic product. The petition should also describe the nonsynthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance. Additionally, the petition should summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a nonsynthetic substance or alternative cultural methods.

When petitioning for the removal of a synthetic substance from the National List the petition must state why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.

When petitioning for the inclusion on the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should not be permitted in the production or handling of an organic product.

When petitioning for the removal from the National List of a nonsynthetic substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should be permitted in the production or handling of an organic product.

When petitioning for the addition to the National List of a nonagricultural (nonorganic)substance state why the substance is necessary for the production or

handling of an organic product. The petition should also describe the agricultural or organic substances that could be used in place of the petitioned nonagricultural substance.

When petitioning for the removal from the National List of a nonagricultural (nonorganic)substance state why the substance is not necessary for the production or handling of an organic product. The petition should also describe the agricultural or organic substances that could be used in place of the petitioned nonagricultural substance.

When petitioning for the addition or removal from the National List of a nonorganic agricultural substance in section 205.606, state why the substance is necessary, or not necessary for the production or handling of an organic product. The petition should also describe the organic substances that could be used in place of the petitioned nonorganic agricultural substance.

13. A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:
    (a) Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.
    (b) ``Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.
    (c) Each page containing CBI material must have ``CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and ``CBI."
    (d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.
    (e) Each page with CBI-deletions should be marked ``CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and ``CBI- deleted."
    (f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, ``pages 7 through 10 have been CBI-deleted.")

(g) All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential. However, the National List substance evaluations will involve a public and open process. Failure to provide complete information may limit the ability of the technical advisory panel to conduct a comprehensive analysis of the substance or prevent the National Organic Standards Board from making a recommendation to the Secretary. Nonconfidential information will be available for public inspection. The NOP Program Manager may request additional information from the petitioner following receipt of the petition. In accordance with the Paperwork Reduction Act of 1980, Public Law 44 U.S.C. 3501 et seq., the information collection requirements contained in this notice have been previously approved by OMB and were assigned OMB control number 0581-0181.

Authority: 7 U.S.C. 6501-6522.

Dated: July 7, 2000. Sharon Bomer Lauritsen, Acting Deputy Administrator, Transportation and Marketing. [FR Doc. **00-17689 Filed** 7-12-**00**; 8:45 am] BILLING CODE 3410

[Federal Register: July 13, 2000 (Volume 65, Number 135)] [Proposed Rules]
[Page 43259-43261]
[DOCID:fr13jy00-20]

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

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DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
7 CFR Part 205
[TM-**00**-04] RIN 0581-AA40

Submission of Petitions for Evaluation of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling

AGENCY: Agricultural Marketing Service, USDA.
ACTION: Notice of Guidelines and Call for National List Petitions.

SUMMARY: The Organic Foods Production Act of 1990, as amended, (Act) requires the Secretary of Agriculture (Secretary) to establish a National List of Allowed and Prohibited Substances (National List) which identifies the synthetic substances that may be used, and the nonsynthetic substances that cannot be used, in organic production and handling operations.

The Act authorizes the National Organic Standards Board (NOSB) to develop and forward to the Secretary a recommended Proposed National List, and subsequent proposed amendments to it. The Act provides that persons may petition the NOSB to evaluate a substance for inclusion on or removal from the National List. This notice explains who can submit a petition, for what substances a petition can be submitted, and the information that should be included in a submitted petition. All submitted petitions will be evaluated by the Department of Agriculture's (USDA) National Organic Program (NOP) for completeness. If there is incomplete information, petitioners will be given a reasonable opportunity to provide the missing information. Petitioners should realize that providing incomplete information may increase the evaluation time or result in no substance evaluation. This notice also provides the name and address of the person to whom a petition should be submitted.

ADDRESSES: Petitions should be submitted in duplicate to: National Organic Standards Board, c/o Robert Pooler, Agricultural Marketing Specialist, USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268, P.O. Box 96456, Washington, D.C. 20090-6456. Phone: 202/720-3252. Fax: 202/205- 7808. e-mail: nlpetition@usda.gov. Petitioners are encouraged to submit the required information through one system of submission (mail, fax or e-mail).

FOR FURTHER INFORMATION CONTACT: Keith Jones, Program Manager, National Organic Program, USDA/AMS/TM/NOP, Room 2945-So., Ag Stop 0268, P.O. Box 96456, Washington, D.C. 20090-6456. Phone: 202/720-3252. Fax: 202/690- 3924. e-mail: keith.jones@usda.gov.

SUPPLEMENTARY INFORMATION: To help readers better understand the petition process, we have provided answers to some frequently asked questions about the National List and the petition process.

What Is the Purpose and Timing of This Notice?

The NOSB submitted a Proposed National List to the Secretary that was subsequently published on March 13, 2000, as part of the NOP proposed rule, 65 FR 13512-13658, (2000). Based on information supplied to the NOSB by trade associations, certification organizations and other organic industry sources, there are many substances currently used in organic production and handling that have not been evaluated by the NOSB for inclusion on the National List. Evaluations of these materials must be expedited to prevent the disruption of many well-established and accepted production, handling and processing systems. The NOP and the NOSB will be developing a workplan to process the potential evaluation of the numerous substances which may be presented to the NOSB and the NOP. Therefore, the organic industry is encouraged to initiate notification to the NOSB and the NOP on which substances should receive priority for evaluation. Substances that are petitioned and under evaluation by the NOSB will be announced on the NOP website: www.ams.usda.gov/nop. Interested individuals or groups can provide information or commentary to the NOSB or NOP for any substance being evaluated by the NOSB.

How Are National List Decisions Made?

The NOSB reviews information from various sources in evaluating substances for inclusion on or removal from the National List. Sources include Technical Advisory Panels (TAP), the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and the testimony of the public. TAP reviews assist the NOSB in evaluating substances being considered for addition to or removal from the National

List. The NOP, on behalf of the NOSB, establishes contracts to conduct the TAP with qualified individuals or organizations who have specialized knowledge of the petitioned substances. These reviewers have expertise in such fields as organic production and handling, veterinary medicine, chemistry, or food handling and preparation. All contractors, whether an individual or an organization, must meet USDA contract requirements including the prevention of conflict of interest. Recent TAP reviews conducted for the NOSB have been performed under contract by the Organic Materials Review Institute (OMRI). However, the NOP on behalf of the NOSB may contract with any individual or organization having the necessary technical expertise to conduct TAP reviews for NOSB substance evaluations. TAP reports and the NOSB recommendations for each substance are submitted to the Secretary. The Secretary evaluates the recommendations and other documentation regarding each substance for inclusion on or removal from the National List. The Act requires that the initial Proposed National List and subsequent proposed amendments to it be published in the Federal Register for public comment.

How Long Can a Substance Appear on the National List and Will the List Change?

The Act (7 U.S.C. 6517(e)) requires that substances appearing on the National List be reviewed by the NOSB and the Secretary at least once every 5 years following implementation of the NOP. Once a substance evaluation is
[[Page 43260]]
completed and a recommendation is forwarded to the Secretary, the NOSB will not reevaluate its decision within the 5 year period unless substantive new information becomes available.

What Criteria Does the NOSB Use to Evaluate Petitioned Substances?

The Act (7 U.S.C. 6518(m)) requires that the NOSB consider the following criteria for each substance evaluated: (1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems; (2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment; (3) The probability of environmental contamination during manufacture, use, misuse or disposal of such substance; (4) The effect of the substance on human health; (5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the substance's physiological effects on soil organisms (including the salt index and solubility of the soil), crops and livestock; (6) The alternatives to using the substance in terms of practices or other materials; and, (7) It's compatibility with a system of sustainable agriculture.

How Does the NOSB Evaluate Substances Such as Processing Aids or Adjuvants?

In addition to the criteria cited in the Act, the NOSB developed internal guidelines for evaluating processing substances such as synthetic processing aids or adjuvants for inclusion on or removal from the National List during their February 1999 meeting. For specific information about these guidelines, please refer to the USDA NOP website: www.ams.usda.gov/nop/nosbfeb99.html, or write the Program Manager, National Organic Program, USDA/AMS/TM/NOP, Room 2945-So, Ag Stop 0268, PO Box 96456, Washington, D.C. 20090-6456. Phone: 202/720- 3252. Fax: 202/690-3924. e-mail: keith.jones@usda.gov.

When Can the NOSB be Petitioned?

The NOSB can be petitioned at any time for substances not previously evaluated by the NOSB. For substances receiving a prior recommendation by the NOSB restricting or prohibiting its use, a petition may be **filed** only when significant new information may alter the established NOSB recommendation. However, the NOSB and the NOP expects that amending the National List will be a continuous process. For instance, the National List may need to be amended to accommodate development of new substances or technologies in organic production or handling of foods. Recommendations to amend the National List result from the review and deliberation of the TAP reports and other information by the NOSB Committees (Crop, Livestock, Processing or Materials). These committees forward their recommendations to the entire NOSB which considers, then accepts, modifies or rejects these recommendations during scheduled public meetings or conferences conducted periodically, as needed.

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What Information Has to be Included in the Petition?

A petition seeking evaluation of a substance must indicate within which of the following categories the substance is being petitioned for inclusion on or removal from the National List: (1) Synthetic substance's allowed for use in organic crop production; (2) Nonsynthetic substances prohibited for use in organic crop production; (3) Synthetic substances allowed for use in organic livestock production; (4) Nonsynthetic substances prohibited for use in organic livestock production; and (5) Nonagricultural (nonorganic) substances allowed in or on processed products labeled as ``organic" or ``made with organic (specified ingredients)." The petition must also include, as applicable, the following information: 1. The substance`s common name. 2. The manufacturer`s name, address and telephone number. 3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. 4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance`s mode of action must be described. 5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential

Business Information (CBI) listed in #13. 6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. 7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. 8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. 9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock. 10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. 11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. 12. A ``Petition Justification Statement'' which provides justification for one of the following actions requested in the petition:

[[Page 43261]]

When petitioning for the inclusion of a synthetic substance on the National List, the petition should state why the synthetic substance is necessary for the production or handling of an organic product. The petition should also describe the nonsynthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance. Additionally, the petition should summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a nonsynthetic substance or alternative cultural methods. When petitioning for the removal of a synthetic substance from the National List the petition must state why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product. When petitioning for the inclusion on the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should not be permitted in the production or handling of an organic product. When petitioning for the removal from the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should be permitted in the production or handling of an organic product. 13. A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below: (a) Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim. (b) ``Trade secrets'' (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy. (c) Each page containing CBI material must have ``CBI Copy'' marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and ``CBI.'' (d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text

where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy. (e) Each page with CBI-deletions should be marked ``CBI-deleted'' at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and ``CBI-deleted." (f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, ``pages 7 through 10 have been CBI-deleted.") (g) All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential. However, the National List substance evaluations will involve a public and open process. Nonconfidential information will be available for public inspection. The NOP Program Manager may request additional information from the petitioner following receipt of the petition. In accordance with the Paperwork Reduction Act of 1980, Public Law 44 U.S.C. 3501 et seq., the information collection requirements contained in this notice have been previously approved by OMB and were assigned OMB control number 0581-0181.

Authority: 7 U.S.C. 6501-6522.

Dated: July 7, 2000. Sharon Bomer Lauritsen, Acting Deputy Administrator, Transportation and Marketing. [FR Doc. **00-17689 Filed** 7-12-**00**; 8:45 am] BILLING CODE 3410

Addendum B: Comments from the Organic Materials Review Institute (OMRI) on the petition process – Submitted to the NOSB on October 22, 2003

Changes needed to the petition

1. Statutory and regulatory criteria. Cite the statutory exemptions specified in §6517(c) of OFPA.
2. Specify the criteria established in the final rulemaking for processing substances .[1]
3. Require a justification for nonorganic, non-agricultural substances petitioned for use in handling.
4. Clarify that petitions can be filed in any one of three categories: (a) add a substance, (b) remove a substance, or (c) amend annotations for current listings in the *National Lis*t. For removing a material or amending an annotation, the petitioner may cite existing data and documents already on file with the NOP and NOSB provided that it is adequate for fulfilling the requirements of a complete petition.

An additional document that provides directions and clarification of the following definitions would be of value to petitioners.

1. Differentiate between synthetic and non-synthetic substances used in crops and livestock production and between agricultural and non-agricultural (nonorganic) substances used in handling.
2. Develop examples to enable petitioners to determine if a given substance is agricultural or non-agricultural.

[1] 7 CFR 205.600(b). The Petition Guidelines should also establish that the §205.600(b) criteria apply to all nonorganic (non-agricultural) substances used in processing and are not limited to "synthetic processing aids and adjuvants" as currently stated in the July 13, 2000 *Federal Register* notice.

3. State the statutory conditions necessary to exempt synthetic substances as well as the criteria that a petition justification must meet to invoke the statutory exemption. List the substances or categories of substances that are explicitly prohibited by OFPA and the NOP Rule.
4. Routinely publish a list of denied petitions to discourage re-petitions except where new information or statutory interpretation is available.
5. Clarify the limitations placed by claims of Confidential Business Information on a full technical review by the TAP contractor and the NOSB, including the possibilities for delays caused by insufficient information when CBI is claimed.

Addendum C: Excerpts from Senate Report

Review of the National List references in the "Report of the Committee on Agriculture, Nutrition and Forestry, United States Senate to accompany S.2830, together with additional and minority views, gives further explanation of the Title XVI-Organic Certification Program. In the section entitled "National List", a more thorough explanation of the philosophy behind the National List is described. Specifically, the report states, "The committee does not intend to allow the use of many synthetic substances. This legislation has been carefully written to prevent widespread exceptions or "loopholes" in the organic standards which would circumvent the intent of this legislation".

As for the intention of the specific categories listed in OFPA the report states, "The Board and the Secretary may consider allowing the use of synthetic active ingredients in the following categories only: pheromones; copper and sulfur compounds, soaps; horticultural oils; toxins derived from bacteria; treated seed; fish emulsions, vitamin and minerals; livestock parasiticides and medicines, and production aides such as machinery cleansers".

The report addressed the limited scope of the categories: "Almost all State and private organization standards also provide for certain exceptions from the no-synthetic rule, some more explicitly than others. In deciding upon an acceptable list if materials of the Organic Standards Board and the Secretary to consider, the Committee surveyed State and private regulations to ensure that the above categories, while more restrictive than most of the current standards, will indeed protect the integrity of the organic product while at the same time provide the producer a reasonable amount of flexibility on production material